

**REMARKS**

Claims 1-6 and 9-22 are pending in the present application. Claims 1-6 and 8-22 stand rejected as being allegedly rendered obvious by claims 1-10 of U.S. Patent No. 6,406,498 (the '498 patent) under the judicially created doctrine of obviousness-type double patenting. Applicant traverses this rejection. Claims 1-6 and 8-22 recite a composite material comprising a bioglass or bioceramic reinforcing component having a "particle size of between 60  $\mu\text{m}$  and 150  $\mu\text{m}$ ." Claims 1-10 of the '498 patent make no mention of the particle size of the bioabsorbable or bioactive particles and therefore claims 1-10 do not teach each and every element of claims 1-6 and 8-22.

The Examiner states that "optimizing the amount and particle size of bioglass so as to achieve the [claimed] composite. . . would have been within the scope of a skilled artisan." As Applicant has stated before, there is no teaching in the art that particle size of the bioglass or bioceramic reinforcing component is a result-effective variable. (See MPEP 2144.05 "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.").

Further, as Applicant has stated before, the claimed range of particle size of the bioceramic or bioglass reinforcing component of between 60 $\mu\text{m}$  and 150 $\mu\text{m}$  is critical. Specifically, as Applicant pointed out in the October 25, 2004 Response to Office Action, the August 25, 2003 Response to Office Action and the June 28, 2004 Response to Office Action, this claimed range achieves unexpected results relative to the prior art. The specification states at page 6, lines 14-22:

[t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

The increased biocompatibility seen with coarser particles is supported by Example 11 of the present specification which compares histological studies of

composite plates with finer hydroxyapatite powder (7.43 microns) and coarser hydroxyapatite particles (80 +/- 20 microns). As shown in Example 11:

in histological studies it was clearly seen, that in and around the composite plates with finer hydroxyapatite powder [7.43 microns] there existed significantly more giant cells than in the tissue of reference animals containing composite plates with coarser hydroxyapatite particles [80 +/- 20 microns]. Thus, coarser hydroxyapatite particles were shown to be more biocompatible.

Page 13, lines 18-23.

Applicant has therefore shown that the claimed particle size of 60  $\mu$ m to 150  $\mu$ m of the bioglass or bioceramic reinforcing component is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue. For at least this reason, Applicant submits that claims 1-6 and 8-22 are not rendered obvious by the '498 patent.

#### CONCLUSION

Applicant submits that the subject application is in condition for allowance, and respectfully requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon Deposit Account No. 11-0600.

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Respectfully submitted,

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